K101032

510k Summary

Date Prepared: May 12, 2010

Company Information

Sponsor/Manufacturer:	BioPro , Inc.
Address:	17 Seventeenth St.
	Port Huron, MI 48060
Owner/Operator:	Pat Pringle
ERN:	1833506
Contact:	David Mrak
Title:	Director of Product Development
Phone:	(810) 982-7777
Email:	mrakd@bioproimplants.com

JUN - 3 2010

Contract sterilizer:	Tri-State Hospital Supply
Address:	301 Catrell
	Howell, MI 48843
ERN:	1824619
Contact:	Karen Kowalczyk
Title:	QA Director
Phone:	517-545-5400

Representative/Consultant

N/A

Device Information

Proprietary Name:	HBS (Headless Bone Screw)
Common Name:	Smooth or threaded metallic bone fixation fastener
Classification Name:	Screw Fixation Bone
Classification Panel:	Orthopedic (OR)
Regulatory Class:	Class II per 21 CFR §888.3390
Product Code:	HWC
Predicate Device:	K020791; 510k 991197

Performance and Voluntary Standards

No Performance Standards applicable to this device have been adopted under Section 514 of the Act.

Intended Use

The intended use and indications of the modified device are the same as the intended uses and indications for the unmodified device however use in the skull has been omitted. The device is being offered sterile as opposed to non-sterile and additional lengths have been added.

Sterilization Information

Method:	Ethylene oxide (EtO), fixed chamber
Sterility Assurance Level:	10^{-6}
Validation Method:	***AAMI Overkill Method***
Sterilization Site:	Tri-State Hospital Supply Howell, MI **ERN:** 1824619
EO and ECH residuals:	The EtO residuals testing protocol requires residuals as per ANSI/AAMI/ISO 10933-7 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals, paragraph 4.3.1 Permanent Contact Devices; as per this standard, the average daily dose of EO to the patient shall not exceed 0.1 mg/day, and the maximum EO dose shall not exceed 20 mg in the first 24 hours, 60 mg in the first 30 days, and 2.5 g in a lifetime. For ECH, the average daily dose shall not exceed 2 mg/day, and the maximum ECH dose shall not exceed 12 mg in the first 24 hours, 60 mg in the first 30 days, and 50 g in a lifetime. Provided the measured EO residual is below 0.1 mg, the release rates cannot exceed these limits; similarly, if the measured ECH residual is below 2 mg, the release rates cannot exceed these limits.
Packaging Information:	Peelable Tyvek® Lids, double Blister, in a cardboard box, and tamper resistant outer labels.

Original unmodified predicate device:

The original unmodified device was known as the HBS. The device was submitted under 510k 020791. The device was submitted by Millennium Medical Technologies, Inc. and was distributed by them. BioPro has obtained the rights to the 510k and has been legally marketing the device since 2008.

Description:

The BioPro HBS screw is designed for hand, foot and small bone fragment repairs or fusions. Uses include osteotomy fixation, joint arthrodesis or post traumatic fragment repair. The BioPro HBS screw is made of titanium in compliance with ASTM F136-02a. Titanium is a biocompatible material that is readily available and commonly used in implanted medical devices. The screw is similar to other screws available on the market. The HBS screw is cannulated and comes in two diameters, 2.5mm and 3.0mm. Each screw is available in several lengths ranging from 6mm up to 40mm in length the original system was available up to 30mm lengths and the original screws

were provided non sterile. The new versions of the screw will be provided sterile. The screws have a Torx driving head.

Device Comparison:

Feature	Substantially Equivalent Device(s)	BioPro HBS Screw
Material	Vilex 510k 991197 Titanium ASTM F136-02a HBS 510k 020791	Titanium ASTM F136-02a
Sizes	Vilex 2.0-6.5mm Osteomed K010783 2.0-2.4mm HBS (original) 2.5-3.0mm up to 30mm lengths	2.5-3.0mm 6mm to 40mm lengths
Design	Vilex: Cannulated with hexagonal drive Osteomed: Cannulated with Cruciform Drive	Cannulated with Torx drive
Sterilization	Vilex: provided non-sterile Osteomed: Provided non-sterile HBS Original	Provided sterile via ETO Sterilization

Summary of modifications:

The original screws were provided non-sterile and were available in two diameters, 2.5mm and 3.0mm with lengths up to 30mm

The modified screws in this submission will now be provided sterile and the lengths will increase to 40mm with no changes to the diameter of the screw.

Performance testing: The implant is made of titanium to the ASTM standards that are recognized consensus standards of the FDA. There is an ASTM standard F-543 entitled: "Standard Specification and Test Methods for Metallic Medical Bone Screw" An engineering rational is included in this submission in regards to this specification.

Device Information:

Intended Use:

This device:

1. has been previously submitted to the FDA for identical or different intended uses. Under 510k 0207091
2. is not currently being reviewed for different intended uses by the same or a different branch within the ODE

3. Has not been previously cleared by the FDA for different intended uses.

Indications:

HBS-Mini (2.5mm)	HBS Standard (3.0mm)
Scaphoid fractures	Scaphoid fractures
Lunate fractures	Carpal fractures and non-unions
Capitate	Capitellum fractures
Trapezial fractures	Metacarpal fractures
Metacarpal and metatarsal fractures	Phalangeal fractures
Phalangeal fractures	Distal radial fractures
Radial head fractures	Radial head fractures
Ulnar styloid fractures	Ulnar styloid fractures
Osteo-chondral	Small joint fusions
Small joint fustions	Humeral head fractures
	Glenoid fractures
	Intercarpal fusions
	Interphalangeal fractures
	Metatarsal osteotomies
	Tarsal fusions
	Malleolar fractures
	Patellar fractures
	Osteo-chondral fractures

Contraindications:

1. Comminuted bone surface that would mitigate against screw placement.
2. Pathologic conditions of bone such as osteopenia which would impair the ability to securely fix the staple.
3. Foreign body sensitivity to metals specifically titanium. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.

Materials:

Titanium (ASTM F136-02a)

Packaging/Sterilization Information:

The packaging will consist of a double blister system; both blisters will use a tyvek backing and a polyethylene tray. A "peel" type opening will allow reliable removal of the product inside the sterile field. This packaging will be certified and tested according to current medical packaging requirements. All components will be sterilized using the ethylene oxide gas sterilization method and validated per ANSI/AAMI ST 27-1988 prior to marketing the device. See section 14 for sterilization validation information. With an SAL of 10^{-6}.

Labeling

Draft labeling for this device is included.

Verification Activities

Engineering rational provided for testing of the screws. No changes were made to the diameters so there would be no changes to the torsional strength. A complete summary of the studies as they relate to the sterilization are included in Attachment "B". of the submission. Also included is the complete risk analysis for the sterilization and packaging in Attachment "A". Based on these studies we believe the subject device is safe and affective

Conclusion:

The primary change for this special 510k submission was the change for non-sterile screws to sterile screws. The design of the screw is unchanged from our predicate device with the exception of the length increase of 10mm. Not only are the original sizes substantially equivalent to our existing device, they are identical in design and have not changed. The additional lengths were added and the 510k 991197 was used as the predicate for those changes. Considering that the design has not changed and the parts are now sterile we believe that we have shown the device to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

BioPro, Inc.
% Mr. David Mrak
Director of Product Development
2929 Lapeer Road
Port Huron, Michigan 48060

JUN - 3 2010

Re: K101030
Trade/Device Name: HBS Headless Bone Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: May 17, 2010
Received: May 17, 2010

Dear Mr. Mrak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101030

Device Name: BioPro HBS (Headless Bone Screw)

Indications for Use:

HBS-Mini (2.5mm)	HBS Standard (3.0mm)
Scaphoid fractures	Scaphoid fractures
Lunate fractures	Carpal fractures and non-unions
Capitate	Capitellum fractures
Trapezial fractures	Metacarpal fractures
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Phalangeal fractures	Distal radial fractures
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Osteo-chondral	Small joint fusions
Small joint fustions	Humeral head fractures
	Glenoid fractures
	Intercarpal fusions
	Interphalangeal fractures
	Metatarsal osteotomies
	Tarsal fusions
	Malleolar fractures
	Patellar fractures
	Osteo-chondral fractures

Prescription Use__X____ AND/OR Over-The-Counter Use_____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101030